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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,846	10/10/2003	William Richard Heineman	0091830/0517360	2736

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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/683,846	**Applicant(s)** HEINEMAN ET AL.	
	Examiner Jacqueline DiRamio	**Art Unit** 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 15 August 2005.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1 – 12 in the reply filed on August 15, 2005 is acknowledged. The traversal is on the ground(s) that the two methods described are so closely related that the Examiner could search the entire application without undue burden. This is not found persuasive because the two groups presented in the restriction requirement do reflect independent and patentably distinct methods, wherein the search required for Group I would not necessarily overlap the search required for Group II. The only overlapping limitations are the use of a finished water sample and addition of a buffering or chelating agent, which is not sufficient to combine the methods of the two groups. Therefore, the two groups would require undue burdensome search and examination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13 – 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

The disclosure is objected to because of the following informalities:

On page 5, paragraph [0016], the first sentence is missing a linking verb in the phrase, "molecular recognition and signal emission in assays_ generally understood."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "selecting at least one first molecular recognition element that identifies", which is vague and indefinite because it is unclear if this is a separate step, because no semi-colon is found at the end of the phrase before the next step, and further the term "that identifies," is unclear as to what the recognition element is identifying and how it is doing the identifying.

Claim 7 recites the term "said first molecular recognition elements," which lacks antecedent basis because there is not a plurality of recognition elements found in claim 1.

Claim 8 recites the term "said first or second molecular recognition element," which lacks antecedent basis because there is not a second molecular recognition element recited in claim 1.

Claim 12, which is dependent on claim 3, recites the term "said solid phase," which lacks antecedent basis, because a "solid phase" is not recited in claim 3, only in claim 11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 4, 6, 7 and 10 – 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Pyle et al. (US 5,821,066).

Pyle et al. teach a simple, rapid method for detection of specific microorganisms, particularly in potable water sources (finished water) and water storage areas (see column 6, lines 48-53). The method comprises the steps of:

analyzing a sample for a particular target species in food or water, and additionally determining if the species is viable in the food or water sample;

selecting and providing an antibody (first molecular recognition element) that specifically binds to a particular species of target bacteria in the sample of water;

mixing (flowing) the liquid (sample) suspected to contain the target bacteria with the specific antibody (first recognition element);

capturing the bacteria (biological agent) present in the sample with the specific antibody (first recognition element) through binding;

emitting a fluorescence signal, which indicates the presence of the target bacteria in the sample (see example 3, columns 17-18 in particular).

With respect to Applicant's claims 2 – 4, the bacteria that has been captured by binding with the specific antibody is next treated with a specific fluorescent conjugated antibody (second molecular recognition element) that also binds to the captured bacteria (see column 18, lines 2-10 in particular). The fluorescent label provides the emitted fluorescence signal to indicate the presence of the target bacteria in the sample, wherein the signal is quantifiable using an image analysis system (see column 18, lines 30-42 in particular).

With respect to Applicant's claim 6, the signal emission is capable of fluorescence detection, as discussed above (see column 18, lines 1-42).

With respect to Applicant's claim 7, the element used by Pyle et al. to specifically bind to the target bacteria is an antibody (see column 17, lines 53-58 in particular).

With respect to Applicant's claim 10, the biological agents detected by the method of Pyle et al. mainly consist of pathogenic bacteria (see column 16, lines 54-56 and column 17, lines 53-56 in particular).

With respect to Applicant's claims 11 and 12, the antibody (first molecular recognition element) used to specifically bind to the target bacteria is coated on a solid phase, particularly immunomagnetic beads (see column 17, lines 53-58 and column 18, lines 55-60).

Claims 1 – 5 and 7 – 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Fritsch et al. (US 2003/0108922).

Fritsch et al. teach an electrochemical detection method for pathogens and toxins in water supplies, particularly drinking water (finished water). The method comprises the steps of:

analyzing a sample suspected of having a target analyte (biological agent), particularly determining if the analyte is a water-born pathogen;

selecting and providing a primary analyte binding material (first molecular recognition element), which targets the biological agent in the sample;

introducing (flowing) the sample to be tested for a specific analyte to the assay structure, which contains the primary analyte binding material (first molecular recognition element);

capturing the biological analyte in the sample through binding to the primary analyte binding material (first molecular recognition element);

creating a current (emitting a signal) within the assay structure via a electrochemically active material, which indicates the presence of the analyte in the sample (see paragraphs [0024], [0025], [0036] and [0038] in particular).

With respect to Applicant's claims 2 – 4, a secondary analyte binding material (second molecular recognition element) is utilized, which further associates and targets the captured target agent and is manipulated through covalent binding with an electrochemically active molecule, which contains an electrolabeling material, which is capable of causing the created current (emission of signal), which provides the quantifiable signal of the biological agent's presence in the water sample (see paragraphs [0025], [0039], [0046] and Figure 1).

With respect to Applicant's claim 5, the signal emission generated through a created current is detected electrochemically (see paragraphs [0024] and [0025]).

With respect to Applicant's claim 7, the primary analyte binding material (first molecular recognition element) includes antibodies, lipid layers, and protein binding materials, such as styrene or polynucleotides (see paragraph [0038]).

With respect to Applicant's claims 8 and 9, the sample is treated with an electrochemically active material, which contains an electrolabeling material and either a metal ion, a redox enzyme, a metalloprotein, or a chelating agent. The electrochemically active material is added along with the secondary analyte binding material (second molecular recognition element) to bind to the target agent and create the electrochemical signal, without interfering with the primary analyte binding material (first molecular recognition element) (see Figure 1, paragraph [0063], and claim 2 in particular).

With respect to Applicant's claim 10, the method presented by Fritsch et al. is utilized for detection of biomolecules, bacteria, viruses, toxins, pathogens and other microorganisms (see paragraphs [0024] and [0036]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritsch et al. (US 2003/0108922) in view of Pyle et al (US 5,821,066).

The Fritsch et al. reference, which has been discussed in the 102(e) rejection above, fails to teach that the signal emission is capable of fluorescence detection or that the first molecular recognition element is associated with a solid phase.

Pyle et al. teach a simple, rapid method for detection of specific microorganisms, particularly in potable water sources (finished water) and water storage areas (see column 6, lines 48-53). The method utilizes fluorescence detection through a fluorescently labeled antibody, which provides confirmation that the bacteria captured is indeed the target pathogen, and further, the fluorescence detection allows for qualitative detection under a fluorescence microscope and quantitative detection using an image analysis system (see column 14, lines 37-39 and column 18, lines 30-35). The method of Pyle et al. additionally utilizes a solid phase, in the form of immunomagnetic beads, which are coated with an antibody specific for the target bacteria. The beads effectively bind the target bacteria, forming a bacterium:magnetic bead complex, and rapidly separate the bacteria from the homogenous sample through a magnetic holder (see column 17, lines 53-58 and column 18, lines 55-67 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the method of Fritsch et al. the use of fluorescence detection as taught by Pyle et al. because Pyle et al. teach the benefit of fluorescence detection to provide confirmation that the bacteria captured is indeed the target pathogen, and further, to allow for qualitative detection under a fluorescence microscope and quantitative detection using an image analysis system. It would also have been obvious to one of ordinary skill in the art to include in the method of Fritsch et al. the use of a solid phase, particularly immunomagnetic beads, as taught by Pyle et al. because Pyle et al. teaches the benefit of using the beads to effectively bind the target bacteria, forming a bacterium:magnetic bead complex, and to rapidly separate the bacteria from the homogenous sample through a magnetic holder.

Conclusion

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Tsang et al. (US 2001/0049116) teaches a method for detecting *cryptosporidium parvum* oocysts in finished water utilizing molecular markers and electrochemiluminescence (see abstract and paragraphs [0021], [0033] and [0034]).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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